

respect to a particular drug product upon a finding that—

(A) applying the factors described in subsection (b) of this section to the drug product, the drug product is being diverted; or

(B) there is a significant change in the data that led to the issuance of the regulation.

(Pub. L. 91-513, title II, §204, as added Pub. L. 103-200, §2(b)(1), Dec. 17, 1993, 107 Stat. 2334; amended Pub. L. 104-237, title IV, §401(c), Oct. 3, 1996, 110 Stat. 3108; Pub. L. 109-177, title VII, §712(a)(2), Mar. 9, 2006, 120 Stat. 263.)

AMENDMENTS

2006—Subsec. (e). Pub. L. 109-177 struck out subsec. (e). Text read as follows: “Pursuant to subsection (d)(1) of this section, the Attorney General shall by regulation reinstate the exemption with respect to a particular ephedrine, pseudoephedrine, or phenylpropanolamine drug product if the Attorney General determines that the drug product is manufactured and distributed in a manner that prevents diversion. In making this determination the Attorney General shall consider the factors listed in subsection (d)(2) of this section. Any regulation issued pursuant to this subsection may be amended or revoked based on the factors listed in subsection (d)(4) of this section.”

1996—Subsec. (e). Pub. L. 104-237 added subsec. (e).

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104-237 not applicable to sale of any pseudoephedrine or phenylpropanolamine product prior to 12 months after Oct. 3, 1996, except that, on application of manufacturer of particular drug product, Attorney General may exercise sole and judicially unreviewable discretion to extend such effective date up to additional 6 months, see section 401(g) of Pub. L. 104-237, set out as a note under section 802 of this title.

EFFECTIVE DATE

Section effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103-200, set out as an Effective Date of 1993 Amendment note under section 802 of this title.

PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

§ 821. Rules and regulations

The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals.

(Pub. L. 91-513, title II, §301, Oct. 27, 1970, 84 Stat. 1253; Pub. L. 103-200, §3(a), Dec. 17, 1993, 107 Stat. 2336; Pub. L. 108-447, div. B, title VI, §633(b), Dec. 8, 2004, 118 Stat. 2922.)

AMENDMENTS

2004—Pub. L. 108-447 substituted “listed chemicals” for “the registration and control of regulated persons and of regulated transactions”.

1993—Pub. L. 103-200 inserted before period at end “and to the registration and control of regulated persons and of regulated transactions”.

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103-200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103-200, set out as a note under section 802 of this title.

§ 822. Persons required to register

(a) Period of registration

(1) Every person who manufactures or distributes any controlled substance or list I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.

(2) Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period of such registrations. In no event, however, shall such registrations be issued for less than one year nor for more than three years.

(b) Authorized activities

Persons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

(c) Exceptions

The following persons shall not be required to register and may lawfully possess any controlled substance or list I chemical under this subchapter:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance or list I chemical if such agent or employee is acting in the usual course of his business or employment.

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of the controlled substance or list I chemical is in the usual course of his business or employment.

(3) An ultimate user who possesses such substance for a purpose specified in section 802(25)¹ of this title.

(d) Waiver

The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety.

(e) Separate registration

A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals.

(f) Inspection

The Attorney General is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him.

¹ See References in Text note below.

(g) Delivery of controlled substances by ultimate users for disposal

(1) An ultimate user who has lawfully obtained a controlled substance in accordance with this subchapter may, without being registered, deliver the controlled substance to another person for the purpose of disposal of the controlled substance if—

(A) the person receiving the controlled substance is authorized under this subchapter to engage in such activity; and

(B) the disposal takes place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances.

(2) In developing regulations under this subsection, the Attorney General shall take into consideration the public health and safety, as well as the ease and cost of program implementation and participation by various communities. Such regulations may not require any entity to establish or operate a delivery or disposal program.

(3) The Attorney General may, by regulation, authorize long-term care facilities, as defined by the Attorney General by regulation, to dispose of controlled substances on behalf of ultimate users who reside, or have resided, at such long-term care facilities in a manner that the Attorney General determines will provide effective controls against diversion and be consistent with the public health and safety.

(4) If a person dies while lawfully in possession of a controlled substance for personal use, any person lawfully entitled to dispose of the decedent's property may deliver the controlled substance to another person for the purpose of disposal under the same conditions as provided in paragraph (1) for an ultimate user.

(Pub. L. 91-513, title II, §302, Oct. 27, 1970, 84 Stat. 1253; Pub. L. 98-473, title II, §510, Oct. 12, 1984, 98 Stat. 2072; Pub. L. 103-200, §3(b), Dec. 17, 1993, 107 Stat. 2336; Pub. L. 111-273, §3(a), Oct. 12, 2010, 124 Stat. 2859.)

REFERENCES IN TEXT

This subchapter, referred to in subsecs. (b), (c), and (g)(1), was in the original "this title", meaning title II of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1242, and is popularly known as the "Controlled Substances Act". For complete classification of title II to the Code, see second paragraph of Short Title note set out under section 801 of this title and Tables.

Section 802(25) of this title, referred to in subsec. (c)(3), was redesignated section 802(26) of this title by Pub. L. 98-473, title II, §507(a), Oct. 12, 1984, 98 Stat. 2071, and was further redesignated section 802(27) of this title by Pub. L. 99-570, title I, §1003(b)(2), Oct. 27, 1986, 100 Stat. 3207-6.

AMENDMENTS

2010—Subsec. (g). Pub. L. 111-273 added subsec. (g).

1993—Subsec. (a)(1). Pub. L. 103-200, §3(b)(1), inserted "or list I chemical" after "controlled substance" in two places.

Subsec. (b). Pub. L. 103-200, §3(b)(2), inserted "or list I chemicals" after "controlled substances" and "or chemicals" after "such substances".

Subsec. (c). Pub. L. 103-200, §3(b)(3), inserted "or list I chemical" after "controlled substance" wherever appearing.

Subsec. (e). Pub. L. 103-200, §3(b)(4), inserted "or list I chemicals" after "controlled substances".

1984—Subsec. (a). Pub. L. 98-473 designated existing provisions as par. (1), struck out provisions relating to dispensing controlled substances, and added par. (2).

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103-200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103-200, set out as a note under section 802 of this title.

FINDINGS

Pub. L. 111-273, §2, Oct. 12, 2010, 124 Stat. 2858, provided that: "Congress finds the following:

"(1) The nonmedical use of prescription drugs is a growing problem in the United States, particularly among teenagers.

"(2) According to the Department of Justice's 2009 National Prescription Drug Threat Assessment—

"(A) the number of deaths and treatment admissions for controlled prescription drugs (CPDs) has increased significantly in recent years;

"(B) unintentional overdose deaths involving prescription opioids, for example, increased 114 percent from 2001 to 2005, and the number of treatment admissions for prescription opioids increased 74 percent from 2002 to 2006; and

"(C) violent crime and property crime associated with abuse and diversion of CPDs has increased in all regions of the United States over the past 5 years.

"(3) According to the Office of National Drug Control Policy's 2008 Report 'Prescription for Danger', prescription drug abuse is especially on the rise for teens—

"(A) one-third of all new abusers of prescription drugs in 2006 were 12- to 17-year-olds;

"(B) teens abuse prescription drugs more than any illicit drug except marijuana—more than cocaine, heroin, and methamphetamine combined; and

"(C) responsible adults are in a unique position to reduce teen access to prescription drugs because the drugs often are found in the home.

"(4)(A) Many State and local law enforcement agencies have established drug disposal programs (often called 'take-back' programs) to facilitate the collection and destruction of unused, unwanted, or expired medications. These programs help get outdated or unused medications off household shelves and out of the reach of children and teenagers.

"(B) However, take-back programs often cannot dispose of the most dangerous pharmaceutical drugs—controlled substance medications—because Federal law does not permit take-back programs to accept controlled substances unless they get specific permission from the Drug Enforcement Administration and arrange for full-time law enforcement officers to receive the controlled substances directly from the member of the public who seeks to dispose of them.

"(C) Individuals seeking to reduce the amount of unwanted controlled substances in their household consequently have few disposal options beyond discarding or flushing the substances, which may not be appropriate means of disposing of the substances. Drug take-back programs are also a convenient and effective means for individuals in various communities to reduce the introduction of some potentially harmful substances into the environment, particularly into water.

"(D) Long-term care facilities face a distinct set of obstacles to the safe disposal of controlled substances due to the increased volume of controlled substances they handle.

"(5) This Act [see Short Title of 2010 Amendment note set out under section 801 of this title] gives the Attorney General authority to promulgate new regulations, within the framework of the Controlled Substances Act [21 U.S.C. 801 et seq.], that will allow patients to deliver unused pharmaceutical controlled

substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion.

“(6) The goal of this Act is to encourage the Attorney General to set controlled substance diversion prevention parameters that will allow public and private entities to develop a variety of methods of collection and disposal of controlled substances, including some pharmaceuticals, in a secure, convenient, and responsible manner. This will also serve to reduce instances of diversion and introduction of some potentially harmful substances into the environment.”

PROVISIONAL REGISTRATION

Section 703 of Pub. L. 91-513, as amended by Pub. L. 99-514, § 2, Oct. 22, 1986, 100 Stat. 2095, provided that:

“(a)(1) Any person who—

“(A) is engaged in manufacturing, distributing, or dispensing any controlled substance on the day before the effective date of section 302 [this section], and

“(B) is registered on such day under section 510 of the Federal Food, Drug, and Cosmetic Act [section 360 of this title] or under section 4722 of the Internal Revenue Code of 1986 [formerly I.R.C. 1954, section 4722 of Title 26],

shall, with respect to each establishment for which such registration is in effect under any such section, be deemed to have a provisional registration under section 303 [section 823 of this title] for the manufacture, distribution, or dispensing (as the case may be) of controlled substances.

“(2) During the period his provisional registration is in effect under this section, the registration number assigned such person under such section 510 [section 360 of this title] or under such section 4722 [section 4722 of Title 26] (as the case may be) shall be his registration number for purposes of section 303 of this title [section 823 of this title].

“(b) The provisions of section 304 [section 824 of this title], relating to suspension and revocation of registration, shall apply to a provisional registration under this section.

“(c) Unless sooner suspended or revoked under subsection (b), a provisional registration of a person under subsection (a)(1) of this section shall be in effect until—

“(1) the date on which such person has registered with the Attorney General under section 303 [section 823 of this title] or has had his registration denied under such section, or

“(2) such date as may be prescribed by the Attorney General for registration of manufacturers, distributors, or dispensers, as the case may be, whichever occurs first.”

§ 823. Registration requirements

(a) Manufacturers of controlled substances in schedule I or II

The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately

competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(b) Distributors of controlled substances in schedule I or II

The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(c) Limits of authorized activities

Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 826 of this title.

(d) Manufacturers of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(e) Distributors of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(f) Research by practitioners; pharmacies; research applications; construction of Article 7 of the Convention on Psychotropic Substances

The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V and shall modify the registrations of pharmacies so registered to authorize them to dispense controlled substances by means of the Internet, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration or such modification of registration if the Attorney General determines that the issuance of such registration or modification would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 824(a) of this title. Article 7 of the Convention on Psychotropic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this subchapter.

(g) Practitioners dispensing narcotic drugs for narcotic treatment; annual registration; separate registration; qualifications; waiver

(1) Except as provided in paragraph (2), practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)

(A) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

(B) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records (in accordance with section 827 of this title) on such drugs; and

(C) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

(2)(A) Subject to subparagraphs (D) and (J), the requirements of paragraph (1) are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule III, IV, or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B) and the narcotic drugs or combinations of such drugs meet the conditions specified in subparagraph (C).

(B) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to a practitioner are that, before the initial dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, the practitioner submit to the Secretary a notification of the intent of the practitioner to begin dispensing the drugs or combinations for such purpose, and that the notification contain the following certifications by the practitioner:

(i) The practitioner is a qualifying physician (as defined in subparagraph (G)).

(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to refer the patients for appropriate counseling and other appropriate ancillary services.

(iii) The total number of such patients of the practitioner at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, unless, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients. A second notification under this clause shall contain the certifications required by clauses (i) and (ii) of this subparagraph. The Secretary may by regulation change such total number.

(C) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to narcotic drugs in schedule III, IV, or V or combinations of such drugs are as follows:

(i) The drugs or combinations of drugs have, under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or section 262 of title 42, been approved for use in maintenance or detoxification treatment.

(ii) The drugs or combinations of drugs have not been the subject of an adverse determination. For purposes of this clause, an adverse determination is a determination published in the Federal Register and made by the Secretary, after consultation with the Attorney General, that the use of the drugs or combinations of drugs for maintenance or detoxification treatment requires additional standards respecting the qualifications of practitioners to provide such treatment, or requires standards respecting the quantities of the drugs that may be provided for unsupervised use.

(D)(i) A waiver under subparagraph (A) with respect to a practitioner is not in effect unless (in addition to conditions under subparagraphs (B) and (C)) the following conditions are met:

(I) The notification under subparagraph (B) is in writing and states the name of the practitioner.

(II) The notification identifies the registration issued for the practitioner pursuant to subsection (f) of this section.

(III) If the practitioner is a member of a group practice, the notification states the names of the other practitioners in the practice and identifies the registrations issued for the other practitioners pursuant to subsection (f) of this section.

(ii) Upon receiving a notification under subparagraph (B), the Attorney General shall assign the practitioner involved an identification number under this paragraph for inclusion with the registration issued for the practitioner pursuant to subsection (f) of this section. The identification number so assigned shall be appropriate to preserve the confidentiality of patients for whom the practitioner has dispensed narcotic drugs under a waiver under subparagraph (A).

(iii) Not later than 45 days after the date on which the Secretary receives a notification under subparagraph (B), the Secretary shall make a determination of whether the practitioner involved meets all requirements for a waiver under subparagraph (B). If the Secretary fails to make such determination by the end of the such 45-day period, the Attorney General shall assign the physician an identification number described in clause (ii) at the end of such period.

(E)(i) If a practitioner is not registered under paragraph (1) and, in violation of the conditions specified in subparagraphs (B) through (D), dispenses narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, the Attorney General may, for purposes of section 824(a)(4) of this title, consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (f) of this section to be inconsistent with the public interest.

(ii)(I) Upon the expiration of 45 days from the date on which the Secretary receives a notification under subparagraph (B), a practitioner who in good faith submits a notification under subparagraph (B) and reasonably believes that the conditions specified in subparagraphs (B) through (D) have been met shall, in dispensing narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, be considered to have a waiver under subparagraph (A) until notified otherwise by the Secretary, except that such a practitioner may commence to prescribe or dispense such narcotic drugs for such purposes prior to the expiration of such 45-day period if it facilitates the treatment of an individual patient and both the Secretary and the Attorney General are notified by the practitioner of the intent to commence prescribing or dispensing such narcotic drugs.

(II) For purposes of subclause (I), the publication in the Federal Register of an adverse determination by the Secretary pursuant to subparagraph (C)(ii) shall (with respect to the narcotic drug or combination involved) be considered to be a notification provided by the Secretary to practitioners, effective upon the expiration of the 30-day period beginning on the date on which the adverse determination is so published.

(F)(i) With respect to the dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, a practitioner may, in his or her discretion, dispense such drugs or combinations for such treatment under a registration under paragraph (1) or a waiver under subparagraph (A) (subject to meeting the applicable conditions).

(ii) This paragraph may not be construed as having any legal effect on the conditions for obtaining a registration under paragraph (1), including with respect to the number of patients who may be served under such a registration.

(G) For purposes of this paragraph:

(i) The term “group practice” has the meaning given such term in section 1395nn(h)(4) of title 42.

(ii) The term “qualifying physician” means a physician who is licensed under State law and who meets one or more of the following conditions:

(I) The physician holds a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties.

(II) The physician holds an addiction certification from the American Society of Addiction Medicine.

(III) The physician holds a subspecialty board certification in addiction medicine from the American Osteopathic Association.

(IV) The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than eight hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause.

(V) The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.

(VI) The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients.

(VII) The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective only for 3 years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the 30-day period preceding the end of the 3-year period involved.

(H)(i) In consultation with the Administrator of the Drug Enforcement Administration, the Administrator of the Substance Abuse and Men-

tal Health Services Administration, the Director of the National Institute on Drug Abuse, and the Commissioner of Food and Drugs, the Secretary shall issue regulations (through notice and comment rulemaking) or issue practice guidelines to address the following:

(I) Approval of additional credentialing bodies and the responsibilities of additional credentialing bodies.

(II) Additional exemptions from the requirements of this paragraph and any regulations under this paragraph.

Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.

(ii) Not later than 120 days after October 17, 2000, the Secretary shall issue a treatment improvement protocol containing best practice guidelines for the treatment and maintenance of opiate-dependent patients. The Secretary shall develop the protocol in consultation with the Director of the National Institute on Drug Abuse, the Administrator of the Drug Enforcement Administration, the Commissioner of Food and Drugs, the Administrator of the Substance Abuse and Mental Health Services Administration and other substance abuse disorder professionals. The protocol shall be guided by science.

(I) During the 3-year period beginning on the date of approval by the Food and Drug Administration of a drug in schedule III, IV, or V, a State may not preclude a practitioner from dispensing or prescribing such drug, or combination of such drugs, to patients for maintenance or detoxification treatment in accordance with this paragraph unless, before the expiration of that 3-year period, the State enacts a law prohibiting a practitioner from dispensing such drugs or combinations of drug.¹

(J)(i) This paragraph takes effect the date referred to in subparagraph (I), and remains in effect thereafter.

(ii) For purposes relating to clause (iii), the Secretary and the Attorney General may, during the 3-year period beginning on December 29, 2006, make determinations in accordance with the following:

(I) The Secretary may make a determination of whether treatments provided under waivers under subparagraph (A) have been effective forms of maintenance treatment and detoxification treatment in clinical settings; may make a determination of whether such waivers have significantly increased (relative to the beginning of such period) the availability of maintenance treatment and detoxification treatment; and may make a determination of whether such waivers have adverse consequences for the public health.

(II) The Attorney General may make a determination of the extent to which there have been violations of the numerical limitations established under subparagraph (B) for the number of individuals to whom a practitioner may provide treatment; may make a determination of whether waivers under subpara-

¹ So in original. Probably should be “combinations of drugs.”.

graph (A) have increased (relative to the beginning of such period) the extent to which narcotic drugs in schedule III, IV, or V or combinations of such drugs are being dispensed or possessed in violation of this chapter; and may make a determination of whether such waivers have adverse consequences for the public health.

(iii) If, before the expiration of the period specified in clause (ii), the Secretary or the Attorney General publishes in the Federal Register a decision, made on the basis of determinations under such clause, that subparagraph (B)(iii) should be applied by limiting the total number of patients a practitioner may treat to 30, then the provisions in such subparagraph (B)(iii) permitting more than 30 patients shall not apply, effective 60 days after the date on which the decision is so published. The Secretary shall in making any such decision consult with the Attorney General, and shall in publishing the decision in the Federal Register include any comments received from the Attorney General for inclusion in the publication. The Attorney General shall in making any such decision consult with the Secretary, and shall in publishing the decision in the Federal Register include any comments received from the Secretary for inclusion in the publication.

(h) Applicants for distribution of list I chemicals

The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under clause (iv) or (v) of section 802(39)(A) of this title. In determining the public interest for the purposes of this subsection, the Attorney General shall consider—

- (1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;
- (2) compliance by the applicant with applicable Federal, State, and local law;
- (3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;
- (4) any past experience of the applicant in the manufacture and distribution of chemicals; and
- (5) such other factors as are relevant to and consistent with the public health and safety.

(Pub. L. 91-513, title II, §303, Oct. 27, 1970, 84 Stat. 1253; Pub. L. 93-281, §3, May 14, 1974, 88 Stat. 124; Pub. L. 95-633, title I, §109, Nov. 10, 1978, 92 Stat. 3773; Pub. L. 98-473, title II, §511, Oct. 12, 1984, 98 Stat. 2073; Pub. L. 103-200, §3(c), Dec. 17, 1993, 107 Stat. 2336; Pub. L. 106-310, div. B, title XXXV, §3502(a), Oct. 17, 2000, 114 Stat. 1222; Pub. L. 107-273, div. B, title II, §2501, Nov. 2, 2002, 116 Stat. 1803; Pub. L. 109-56, §1(a), (b), Aug. 2, 2005, 119 Stat. 591; Pub. L. 109-177, title VII, §712(a)(3), Mar. 9, 2006, 120 Stat. 263; Pub. L. 109-469, title XI, §1102, Dec. 29, 2006, 120 Stat. 3540; Pub. L. 110-425, §3(b), Oct. 15, 2008, 122 Stat. 4824.)

REFERENCES IN TEXT

Schedules I, II, III, IV, and V, referred to in subsecs. (a) to (f) and (g)(2), are set out in section 812(c) of this title.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (g)(2)(C)(i), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

This chapter, referred to in subsec. (g)(2)(J)(ii)(II), was in the original “this Act”, meaning Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1236, as amended. For complete classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables.

AMENDMENTS

2008—Subsec. (f). Pub. L. 110-425, in introductory provisions, inserted “and shall modify the registrations of pharmacies so registered to authorize them to dispense controlled substances by means of the Internet” after “schedule II, III, IV, or V” and substituted “or such modification of registration if the Attorney General determines that the issuance of such registration or modification” for “if he determines that the issuance of such registration”.

2006—Subsec. (g)(2)(B)(iii). Pub. L. 109-469, §1102(1), substituted “unless, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients. A second notification under this clause shall contain the certifications required by clauses (i) and (ii) of this subparagraph. The” for “except that the”.

Subsec. (g)(2)(J)(i). Pub. L. 109-469, §1102(2)(A), substituted “thereafter.” for “thereafter except as provided in clause (iii) (relating to a decision by the Secretary or the Attorney General that this paragraph should not remain in effect).”

Subsec. (g)(2)(J)(ii). Pub. L. 109-469, §1102(2)(B), substituted “December 29, 2006” for “October 17, 2000” in introductory provisions.

Subsec. (g)(2)(J)(iii). Pub. L. 109-469, §1102(2)(C), substituted “subparagraph (B)(iii) should be applied by limiting the total number of patients a practitioner may treat to 30, then the provisions in such subparagraph (B)(iii) permitting more than 30 patients shall not apply, effective” for “this paragraph should not remain in effect, this paragraph ceases to be in effect”.

Subsec. (h). Pub. L. 109-177 substituted “clause (iv) or (v) of section 802(39)(A) of this title” for “section 802(39)(A)(iv) of this title” in introductory provisions.

2005—Subsec. (g)(2)(B)(iii). Pub. L. 109-56, §1(b), substituted “The total” for “In any case in which the practitioner is not in a group practice, the total”.

Subsec. (g)(2)(B)(iv). Pub. L. 109-56, §1(a), struck out cl. (iv) which read as follows: “In any case in which the practitioner is in a group practice, the total number of such patients of the group practice at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, except that the Secretary may by regulation change such total number, and the Secretary for such purposes may by regulation establish different categories on the basis of the number of practitioners in a group practice and establish for the various categories different numerical limitations on the number of such patients that the group practice may have.”

2002—Subsec. (g)(2)(I). Pub. L. 107-273, §2501(1), which directed the substitution of “on the date of approval by the Food and Drug Administration of a drug in schedule III, IV, or V, a State may not preclude a practitioner from dispensing or prescribing such drug, or combination of such drugs,” for “on October 17, 2000, a State may not preclude a practitioner from dispensing or prescribing drugs in schedule III, IV, or V, or combinations of such drugs,” was executed by making the substitution for the phrase which in the original began

with “on the date of the enactment of the Drug Addiction Treatment Act of 2000,” rather than the editorial translation “on October 17, 2000,” to reflect the probable intent of Congress.

Subsec. (g)(2)(J)(i). Pub. L. 107–273, § 2501(2), which directed the substitution of “the date referred to in subparagraph (I),” for “October 17, 2000,” was executed by making the substitution for text which in the original read “the date of the enactment of the Drug Addiction Treatment Act of 2000,” rather than the editorial translation “October 17, 2000,” to reflect the probable intent of Congress.

2000—Subsec. (g). Pub. L. 106–310 designated existing provisions as par. (1), substituted “Except as provided in paragraph (2), practitioners who dispense” for “Practitioners who dispense”, redesignated former pars. (1) to (3) as subpars. (A) to (C), respectively, of par. (1) and redesignated former subpars. (A) and (B) of former par. (2) as cls. (i) and (ii), respectively, of subpar. (B) of par. (1), and added par. (2).

1993—Subsec. (h). Pub. L. 103–200 added subsec. (h).

1984—Subsec. (f). Pub. L. 98–473 amended subsec. (f) generally, substituting provisions relating to registration authority of Attorney General respecting dispensation or conduct of research with controlled research, and separate authority of Secretary respecting registration, for provisions relating to general registration requirements respecting dispensation or conduct of research with controlled or nonnarcotic controlled substances.

1978—Subsec. (f). Pub. L. 95–633 inserted provision relating to the construction of the Convention on Psychotropic Substances.

1974—Subsec. (g). Pub. L. 93–281 added subsec. (g).

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110–425 effective 180 days after Oct. 15, 2008, except as otherwise provided, see section 3(j) of Pub. L. 110–425, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 2005 AMENDMENT

Pub. L. 109–56, §1(c), Aug. 2, 2005, 119 Stat. 591, provided that: “This section [amending this section] shall take effect on the date of enactment of this Act [Aug. 2, 2005].”

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103–200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103–200, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95–633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95–633, set out as an Effective Date note under section 801a of this title.

PROVISIONAL REGISTRATION

For provisional registration of persons engaged in manufacturing, distributing, or dispensing of controlled substances on the day before the effective date of section 822 of this title who are registered on such date under section 360 of this title or section 4722 of Title 26, Internal Revenue Code, see section 703 of Pub. L. 91–513, set out as a note under section 822 of this title.

§ 824. Denial, revocation, or suspension of registration

(a) Grounds

A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant—

(1) has materially falsified any application filed pursuant to or required by this subchapter or subchapter II of this chapter;

(2) has been convicted of a felony under this subchapter or subchapter II of this chapter or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical;

(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;

(4) has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section; or

(5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a–7(a) of title 42.

A registration pursuant to section 823(g)(1) of this title to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 823(g)(1) of this title.

(b) Limits of revocation or suspension

The Attorney General may limit revocation or suspension of a registration to the particular controlled substance or list I chemical with respect to which grounds for revocation or suspension exist.

(c) Service of show cause order; proceedings

Before taking action pursuant to this section, or pursuant to a denial of registration under section 823 of this title, the Attorney General shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended. The order to show cause shall contain a statement of the basis thereof and shall call upon the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but in no event less than thirty days after the date of receipt of the order. Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this subchapter or any other law of the United States.

(d) Suspension of registration in cases of imminent danger

The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety. A failure to comply with a standard referred to in section 823(g)(1) of this title may be treated under this subsection as grounds for immediate suspension of a registration granted under such section. A suspension under this subsection shall

continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.

(e) Suspension and revocation of quotas

The suspension or revocation of a registration under this section shall operate to suspend or revoke any quota applicable under section 826 of this title.

(f) Disposition of controlled substances or list I chemicals

In the event the Attorney General suspends or revokes a registration granted under section 823 of this title, all controlled substances or list I chemicals owned or possessed by the registrant pursuant to such registration at the time of suspension or the effective date of the revocation order, as the case may be, may, in the discretion of the Attorney General, be placed under seal. No disposition may be made of any controlled substances or list I chemicals under seal until the time for taking an appeal has elapsed or until all appeals have been concluded except that a court, upon application therefor, may at any time order the sale of perishable controlled substances or list I chemicals. Any such order shall require the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all such controlled substances or list I chemicals (or proceeds of sale deposited in court) shall be forfeited to the United States; and the Attorney General shall dispose of such controlled substances or list I chemicals in accordance with section 881(e) of this title. All right, title, and interest in such controlled substances or list I chemicals shall vest in the United States upon a revocation order becoming final.

(g) Seizure or placement under seal of controlled substances or list I chemicals

The Attorney General may, in his discretion, seize or place under seal any controlled substances or list I chemicals owned or possessed by a registrant whose registration has expired or who has ceased to practice or do business in the manner contemplated by his registration. Such controlled substances or list I chemicals shall be held for the benefit of the registrant, or his successor in interest. The Attorney General shall notify a registrant, or his successor in interest, who has any controlled substance or list I chemical seized or placed under seal of the procedures to be followed to secure the return of the controlled substance or list I chemical and the conditions under which it will be returned. The Attorney General may not dispose of any controlled substance or list I chemical seized or placed under seal under this subsection until the expiration of one hundred and eighty days from the date such substance or chemical was seized or placed under seal.

(Pub. L. 91-513, title II, §304, Oct. 27, 1970, 84 Stat. 1255; Pub. L. 93-281, §4, May 14, 1974, 88 Stat. 125; Pub. L. 98-473, title II, §§304, 512, 513, Oct. 12, 1984, 98 Stat. 2050, 2073; Pub. L. 100-93, §8(j), Aug. 18, 1987, 101 Stat. 695; Pub. L. 103-200, §3(d), Dec. 17, 1993, 107 Stat. 2337; Pub. L. 103-322, title XXXIII, §330024(e), Sept. 13, 1994, 108 Stat.

2151; Pub. L. 106-310, div. B, title XXXV, §3502(b), Oct. 17, 2000, 114 Stat. 1227.)

REFERENCES IN TEXT

This subchapter, referred to in subsec. (a)(1), (2), was in the original "this title", meaning title II of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1242, as amended, and is popularly known as the "Controlled Substances Act". For complete classification of title II to the Code, see second paragraph of Short Title note set out under section 801 of this title and Tables.

Subchapter II of this chapter, referred to in subsec. (a)(1), (2), was in the original "title III", meaning title III of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1285. Part A of title III comprises subchapter II of this chapter. For classification of Part B, consisting of sections 1101 to 1105 of title III, see Tables.

AMENDMENTS

2000—Subsec. (a). Pub. L. 106-310, §3502(b)(1), substituted "section 823(g)(1) of this title" for "section 823(g) of this title" in two places in concluding provisions.

Subsec. (d). Pub. L. 106-310, §3502(b)(2), substituted "section 823(g)(1) of this title" for "section 823(g) of this title".

1994—Subsec. (g). Pub. L. 103-322 inserted "or chemical" after "such substance" in last sentence.

1993—Subsec. (a). Pub. L. 103-200, §3(d)(1), inserted "or a list I chemical" after "controlled substance" in introductory provisions and par. (2) and inserted "or list I chemicals" after "controlled substances" in par. (3).

Subsec. (b). Pub. L. 103-200, §3(d)(2), inserted "or list I chemical" after "controlled substance".

Subsec. (f). Pub. L. 103-200, §3(d)(3), inserted "or list I chemicals" after "controlled substances" wherever appearing.

Subsec. (g). Pub. L. 103-200, §3(d)(4), inserted "or list I chemicals" after "controlled substances" in two places and "or list I chemical" after "controlled substance" wherever appearing.

1987—Subsec. (a)(5). Pub. L. 100-93 added par. (5).

1984—Subsec. (a)(3). Pub. L. 98-473, §512(1), inserted provisions relating to suspension, etc., recommended by competent State authority.

Subsec. (a)(4). Pub. L. 98-473, §512(2), added par. (4).

Subsec. (f). Pub. L. 98-473, §304, inserted provisions relating to vesting of right, title, and interest in the United States.

Subsec. (g). Pub. L. 98-473, §513, added subsec. (g).

1974—Subsec. (a). Pub. L. 93-281, §4(a), provided for revocation or suspension of a registration pursuant to section 823(g) of this title for failure of a registrant to comply with standards referred to in such section 823(g).

Subsec. (d). Pub. L. 93-281, §4(b), substituted "A suspension under this subsection" for "Such suspension" in third sentence.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103-322 effective 120 days after Dec. 17, 1993, see section 330024(f) of Pub. L. 103-322, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103-200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103-200, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1987 AMENDMENT

Amendment by Pub. L. 100-93 effective at end of fourteen-day period beginning Aug. 18, 1987, and inapplicable to administrative proceedings commenced before end of such period, see section 15(a) of Pub. L. 100-93, set out as a note under section 1320a-7 of Title 42, The Public Health and Welfare.

PROVISIONAL REGISTRATION

Applicability of this section to provisional registrations, see section 703 of Pub. L. 91-513, set out as a note under section 822 of this title.

§ 825. Labeling and packaging**(a) Symbol**

It shall be unlawful to distribute a controlled substance in a commercial container unless such container, when and as required by regulations of the Attorney General, bears a label (as defined in section 321(k) of this title) containing an identifying symbol for such substance in accordance with such regulations. A different symbol shall be required for each schedule of controlled substances.

(b) Unlawful distribution without identifying symbol

It shall be unlawful for the manufacturer of any controlled substance to distribute such substance unless the labeling (as defined in section 321(m) of this title) of such substance contains, when and as required by regulations of the Attorney General, the identifying symbol required under subsection (a) of this section.

(c) Warning on label

The Secretary shall prescribe regulations under section 353(b) of this title which shall provide that the label of a drug listed in schedule II, III, or IV shall, when dispensed to or for a patient, contain a clear, concise warning that it is a crime to transfer the drug to any person other than the patient.

(d) Containers to be securely sealed

It shall be unlawful to distribute controlled substances in schedule I or II, and narcotic drugs in schedule III or IV, unless the bottle or other container, stopper, covering, or wrapper thereof is securely sealed as required by regulations of the Attorney General.

(Pub. L. 91-513, title II, §305, Oct. 27, 1970, 84 Stat. 1256.)

REFERENCES IN TEXT

Schedules I, II, III, and IV, referred to in subsecs. (c) and (d), are set out in section 812(c) of this title.

EFFECTIVE DATE

Section effective on first day of seventh calendar month that begins after Oct. 26, 1970, but with Attorney General authorized to postpone such effective date for such period as he might determine to be necessary for the efficient administration of this subchapter, see section 704(c) of Pub. L. 91-513, set out as a note under section 801 of this title.

§ 826. Production quotas for controlled substances**(a) Establishment of total annual needs**

The Attorney General shall determine the total quantity and establish production quotas for each basic class of controlled substance in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. Production quotas shall be established in terms of quantities of each basic class of controlled substance and not in terms of individual pharmaceutical dosage forms prepared from or containing such a controlled substance.

(b) Individual production quotas; revised quotas

The Attorney General shall limit or reduce individual production quotas to the extent necessary to prevent the aggregate of individual quotas from exceeding the amount determined necessary each year by the Attorney General under subsection (a) of this section. The quota of each registered manufacturer for each basic class of controlled substance in schedule I or II or for ephedrine, pseudoephedrine, or phenylpropanolamine shall be revised in the same proportion as the limitation or reduction of the aggregate of the quotas. However, if any registrant, before the issuance of a limitation or reduction in quota, has manufactured in excess of his revised quota, the amount of the excess shall be subtracted from his quota for the following year.

(c) Manufacturing quotas for registered manufacturers

On or before October 1 of each year, upon application therefor by a registered manufacturer, the Attorney General shall fix a manufacturing quota for the basic classes of controlled substances in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine that the manufacturer seeks to produce. The quota shall be subject to the provisions of subsections (a) and (b) of this section. In fixing such quotas, the Attorney General shall determine the manufacturer's estimated disposal, inventory, and other requirements for the calendar year; and, in making his determination, the Attorney General shall consider the manufacturer's current rate of disposal, the trend of the national disposal rate during the preceding calendar year, the manufacturer's production cycle and inventory position, the economic availability of raw materials, yield and stability problems, emergencies such as strikes and fires, and other factors.

(d) Quotas for registrants who have not manufactured controlled substance during one or more preceding years

The Attorney General shall, upon application and subject to the provisions of subsections (a) and (b) of this section, fix a quota for a basic class of controlled substance in schedule I or II for any registrant who has not manufactured that basic class of controlled substance or ephedrine, pseudoephedrine, or phenylpropanolamine during one or more preceding calendar years. In fixing such quota, the Attorney General shall take into account the registrant's reasonably anticipated requirements for the current year; and, in making his determination of such requirements, he shall consider such factors specified in subsection (c) of this section as may be relevant.

(e) Quota increases

At any time during the year any registrant who has applied for or received a manufacturing quota for a basic class of controlled substance in schedule I or II or for ephedrine, pseudoephedrine, or phenylpropanolamine may apply for an increase in that quota to meet his estimated disposal, inventory, and other requirements during the remainder of that year. In passing upon the application the Attorney Gen-

eral shall take into consideration any occurrences since the filing of the registrant's initial quota application that may require an increased manufacturing rate by the registrant during the balance of the year. In passing upon the application the Attorney General may also take into account the amount, if any, by which the determination of the Attorney General under subsection (a) of this section exceeds the aggregate of the quotas of all registrants under this section.

(f) Incidental production exception

Notwithstanding any other provisions of this subchapter, no registration or quota may be required for the manufacture of such quantities of controlled substances in schedules I and II or ephedrine, pseudoephedrine, or phenylpropanolamine as incidentally and necessarily result from the manufacturing process used for the manufacture of a controlled substance or of ephedrine, pseudoephedrine, or phenylpropanolamine with respect to which its manufacturer is duly registered under this subchapter. The Attorney General may, by regulation, prescribe restrictions on the retention and disposal of such incidentally produced substances or chemicals.

(g) Reference to ephedrine, pseudoephedrine, or phenylpropanolamine

Each reference in this section to ephedrine, pseudoephedrine, or phenylpropanolamine includes each of the salts, optical isomers, and salts of optical isomers of such chemical.

(Pub. L. 91-513, title II, §306, Oct. 27, 1970, 84 Stat. 1257; Pub. L. 94-273, §3(16), Apr. 21, 1976, 90 Stat. 377; Pub. L. 109-177, title VII, §713, Mar. 9, 2006, 120 Stat. 264.)

REFERENCES IN TEXT

Schedules I and II, referred to in text, are set out in section 812(c) of this title.

AMENDMENTS

2006—Subsec. (a). Pub. L. 109-177, §713(1), inserted “and for ephedrine, pseudoephedrine, and phenylpropanolamine” after “for each basic class of controlled substance in schedules I and II”.

Subsec. (b). Pub. L. 109-177, §713(2), inserted “or for ephedrine, pseudoephedrine, or phenylpropanolamine” after “for each basic class of controlled substance in schedule I or II”.

Subsec. (c). Pub. L. 109-177, §713(3), inserted “and for ephedrine, pseudoephedrine, and phenylpropanolamine” after “for the basic classes of controlled substances in schedules I and II”.

Subsec. (d). Pub. L. 109-177, §713(4), inserted “or ephedrine, pseudoephedrine, or phenylpropanolamine” after “that basic class of controlled substance”.

Subsec. (e). Pub. L. 109-177, §713(5), inserted “or for ephedrine, pseudoephedrine, or phenylpropanolamine” after “for a basic class of controlled substance in schedule I or II”.

Subsec. (f). Pub. L. 109-177, §713(6), inserted “or ephedrine, pseudoephedrine, or phenylpropanolamine” after “controlled substances in schedules I and II”, “or of ephedrine, pseudoephedrine, or phenylpropanolamine” after “the manufacture of a controlled substance”, and “or chemicals” after “such incidentally produced substances”.

Subsec. (g). Pub. L. 109-177, §713(7), added subsec. (g). 1976—Subsec. (c). Pub. L. 94-273 substituted “October” for “July”.

EFFECTIVE DATE

Section effective on first day of seventh calendar month that begins after Oct. 26, 1970, but with Attorney

General authorized to postpone such effective date for such period as he might determine to be necessary for the efficient administration of this subchapter, see section 704(c) of Pub. L. 91-513, set out as a note under section 801 of this title.

COORDINATION WITH UNITED STATES TRADE REPRESENTATIVE

Pub. L. 109-177, title VII, §718, Mar. 9, 2006, 120 Stat. 267, provided that: “In implementing sections 713 through 717 and section 721 of this title [amending this section and sections 830, 842, 952, 960, and 971 of this title], the Attorney General shall consult with the United States Trade Representative to ensure implementation complies with all applicable international treaties and obligations of the United States.”

§ 827. Records and reports of registrants

(a) Inventory

Except as provided in subsection (c) of this section—

(1) every registrant under this subchapter shall, on May 1, 1971, or as soon thereafter as such registrant first engages in the manufacture, distribution, or dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand, except that the regulations prescribed under this section shall permit each such biennial inventory (following the initial inventory required by this paragraph) to be prepared on such registrant's regular general physical inventory date (if any) which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply;

(2) on the effective date of each regulation of the Attorney General controlling a substance that immediately prior to such date was not a controlled substance, each registrant under this subchapter manufacturing, distributing, or dispensing such substance shall make a complete and accurate record of all stocks thereof on hand; and

(3) on and after May 1, 1971, every registrant under this subchapter manufacturing, distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by him, except that this paragraph shall not require the maintenance of a perpetual inventory.

(b) Availability of records

Every inventory or other record required under this section (1) shall be in accordance with, and contain such relevant information as may be required by, regulations of the Attorney General, (2) shall (A) be maintained separately from all other records of the registrant, or (B) alternatively, in the case of nonnarcotic controlled substances, be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant, and (3) shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General.

(c) Nonapplicability

The foregoing provisions of this section shall not apply—

(1)(A) to the prescribing of controlled substances in schedule II, III, IV, or V by practitioners acting in the lawful course of their professional practice unless such substance is prescribed in the course of maintenance or detoxification treatment of an individual; or

(B) to the administering of a controlled substance in schedule II, III, IV, or V unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges his patients, either separately or together with charges for other professional services, for substances so dispensed or administered or unless such substance is administered in the course of maintenance treatment or detoxification treatment of an individual;

(2)(A) to the use of controlled substances, at establishments registered under this subchapter which keep records with respect to such substances, in research conducted in conformity with an exemption granted under section 355(i) or 360b(j) of this title;

(B) to the use of controlled substances, at establishments registered under this subchapter which keep records with respect to such substances, in preclinical research or in teaching; or

(3) to the extent of any exemption granted to any person, with respect to all or part of such provisions, by the Attorney General by or pursuant to regulation on the basis of a finding that the application of such provisions (or part thereof) to such person is not necessary for carrying out the purposes of this subchapter.

Nothing in the Convention on Psychotropic Substances shall be construed as superseding or otherwise affecting the provisions of paragraph (1)(B), (2), or (3) of this subsection.

(d) Periodic reports to Attorney General

(1) Every manufacturer registered under section 823 of this title shall, at such time or times and in such form as the Attorney General may require, make periodic reports to the Attorney General of every sale, delivery or other disposal by him of any controlled substance, and each distributor shall make such reports with respect to narcotic controlled substances, identifying by the registration number assigned under this subchapter the person or establishment (unless exempt from registration under section 822(d) of this title) to whom such sale, delivery, or other disposal was made.

(2) Each pharmacy with a modified registration under section 823(f) of this title that authorizes the dispensing of controlled substances by means of the Internet shall report to the Attorney General the controlled substances it dispenses, in the amount specified, and in such time and manner as the Attorney General by regulation shall require, except that the Attorney General, under this paragraph, may not require any pharmacy to report any information other than the total quantity of each controlled substance that the pharmacy has dispensed each month. For purposes of this paragraph, no reporting shall be required unless the pharmacy has met 1 of the following thresholds in the month for which the reporting is required:

(A) 100 or more prescriptions dispensed.

(B) 5,000 or more dosage units of all controlled substances combined.

(e) Reporting and recordkeeping requirements of drug conventions

In addition to the reporting and recordkeeping requirements under any other provision of this subchapter, each manufacturer registered under section 823 of this title shall, with respect to narcotic and nonnarcotic controlled substances manufactured by it, make such reports to the Attorney General, and maintain such records, as the Attorney General may require to enable the United States to meet its obligations under articles 19 and 20 of the Single Convention on Narcotic Drugs and article 16 of the Convention on Psychotropic Substances. The Attorney General shall administer the requirements of this subsection in such a manner as to avoid the unnecessary imposition of duplicative requirements under this subchapter on manufacturers subject to the requirements of this subsection.

(f) Investigational uses of drugs; procedures

Regulations under sections 355(i) and 360(j) of this title, relating to investigational use of drugs, shall include such procedures as the Secretary, after consultation with the Attorney General, determines are necessary to insure the security and accountability of controlled substances used in research to which such regulations apply.

(g) Change of address

Every registrant under this subchapter shall be required to report any change of professional or business address in such manner as the Attorney General shall by regulation require.

(h) Reporting requirements for GHB

In the case of a drug product containing gamma hydroxybutyric acid for which an application has been approved under section 355 of this title, the Attorney General may, in addition to any other requirements that apply under this section with respect to such a drug product, establish any of the following as reporting requirements:

(1) That every person who is registered as a manufacturer of bulk or dosage form, as a packager, repackager, labeler, relabeler, or distributor shall report acquisition and distribution transactions quarterly, not later than the 15th day of the month succeeding the quarter for which the report is submitted, and annually report end-of-year inventories.

(2) That all annual inventory reports shall be filed no later than January 15 of the year following that for which the report is submitted and include data on the stocks of the drug product, drug substance, bulk drug, and dosage forms on hand as of the close of business December 31, indicating whether materials reported are in storage or in process of manufacturing.

(3) That every person who is registered as a manufacturer of bulk or dosage form shall report all manufacturing transactions both inventory increases, including purchases, transfers, and returns, and reductions from inventory, including sales, transfers, theft, destruction, and seizure, and shall provide data on material manufactured, manufactured from other material, use in manufacturing other material, and use in manufacturing dosage forms.

(4) That all reports under this section must include the registered person's registration number as well as the registration numbers, names, and other identifying information of vendors, suppliers, and customers, sufficient to allow the Attorney General to track the receipt and distribution of the drug.

(5) That each dispensing practitioner shall maintain for each prescription the name of the prescribing practitioner, the prescribing practitioner's Federal and State registration numbers, with the expiration dates of these registrations, verification that the prescribing practitioner possesses the appropriate registration to prescribe this controlled substance, the patient's name and address, the name of the patient's insurance provider and documentation by a medical practitioner licensed and registered to prescribe the drug of the patient's medical need for the drug. Such information shall be available for inspection and copying by the Attorney General.

(6) That section 830(b)(3) of this title (relating to mail order reporting) applies with respect to gamma hydroxybutyric acid to the same extent and in the same manner as such section applies with respect to the chemicals and drug products specified in subparagraph (A)(i) of such section.

(Pub. L. 91-513, title II, §307, Oct. 27, 1970, 84 Stat. 1258; Pub. L. 93-281, §5, May 14, 1974, 88 Stat. 125; Pub. L. 95-633, title I, §§104, 110, Nov. 10, 1978, 92 Stat. 3772, 3773; Pub. L. 98-473, title II, §§514, 515, Oct. 12, 1984, 98 Stat. 2074; Pub. L. 106-172, §4, Feb. 18, 2000, 114 Stat. 9; Pub. L. 110-425, §3(c), Oct. 15, 2008, 122 Stat. 4824.)

REFERENCES IN TEXT

Schedules II, III, IV, and V, referred to in subsec. (c), are set out in section 812(c) of this title.

AMENDMENTS

2008—Subsec. (d). Pub. L. 110-425 designated existing provisions as par. (1) and added par. (2).

2000—Subsec. (h). Pub. L. 106-172 added subsec. (h).

1984—Subsec. (c)(1)(A). Pub. L. 98-473, §514(a), substituted "to the prescribing of controlled substances in schedule II, III, IV, or V by practitioners acting in the lawful course of their professional practice unless such substance is prescribed in the course of maintenance or detoxification treatment of an individual" for "with respect to any narcotic controlled substance in schedule II, III, IV, or V, to the prescribing or administering of such substance by a practitioner in the lawful course of his professional practice unless such substance was prescribed or administered in the course of maintenance treatment or detoxification treatment of an individual".

Subsec. (c)(1)(B). Pub. L. 98-473, §514(b), substituted "to the administering of a controlled substance in schedule II, III, IV, or V unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges his patients, either separately or together with charges for other professional services, for substances so dispensed or administered or unless such substance is administered in the course of maintenance treatment or detoxification treatment of an individual" for "with respect to nonnarcotic controlled substances in schedule II, III, IV, or V, to any practitioner who dispenses such substances to his patients, unless the practitioner is regularly engaged in charging his patients, either separately or together with charges for other professional services, for substances so dispensed".

Subsec. (g). Pub. L. 98-473, §515, added subsec. (g).
1978—Subsec. (c). Pub. L. 95-633, §110, inserted provision following par. (3) relating to the construction of the Convention on Psychotropic Substances.

Subsecs. (e), (f). Pub. L. 95-633 added subsec. (e) and redesignated former subsec. (e) as (f).

1974—Subsec. (c)(1)(A). Pub. L. 93-281 substituted "any narcotic controlled substance" for "narcotic controlled substances" and made section applicable to any narcotic controlled substance prescribed or administered in the course of maintenance treatment or detoxification treatment of an individual.

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110-425 effective 180 days after Oct. 15, 2008, except as otherwise provided, see section 3(j) of Pub. L. 110-425, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95-633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95-633, set out as an Effective Date note under section 801a of this title.

§ 828. Order forms

(a) Unlawful distribution of controlled substances

It shall be unlawful for any person to distribute a controlled substance in schedule I or II to another except in pursuance of a written order of the person to whom such substance is distributed, made on a form to be issued by the Attorney General in blank in accordance with subsection (d) of this section and regulations prescribed by him pursuant to this section.

(b) Nonapplicability of provisions

Nothing in subsection (a) of this section shall apply to—

(1) the exportation of such substances from the United States in conformity with subchapter II of this chapter;

(2) the delivery of such a substance to or by a common or contract carrier for carriage in the lawful and usual course of its business, or to or by a warehouseman for storage in the lawful and usual course of its business; but where such carriage or storage is in connection with the distribution by the owner of the substance to a third person, this paragraph shall not relieve the distributor from compliance with subsection (a) of this section; or

(3) the delivery of such a substance for the purpose of disposal by an ultimate user, long-term care facility, or other person acting in accordance with section 822(g) of this title.

(c) Preservation and availability

(1) Every person who in pursuance of an order required under subsection (a) of this section distributes a controlled substance shall preserve such order for a period of two years, and shall make such order available for inspection and copying by officers and employees of the United States duly authorized for that purpose by the Attorney General, and by officers or employees of States or their political subdivisions who are charged with the enforcement of State or local laws regulating the production, or regulating the distribution or dispensing, of controlled substances and who are authorized under such laws to inspect such orders.

(2) Every person who gives an order required under subsection (a) of this section shall, at or before the time of giving such order, make or cause to be made a duplicate thereof on a form to be issued by the Attorney General in blank in accordance with subsection (d) of this section and regulations prescribed by him pursuant to this section, and shall, if such order is accepted, preserve such duplicate for a period of two years and make it available for inspection and copying by the officers and employees mentioned in paragraph (1) of this subsection.

(d) Issuance

(1) The Attorney General shall issue forms pursuant to subsections (a) and (c)(2) of this section only to persons validly registered under section 823 of this title (or exempted from registration under section 822(d) of this title). Whenever any such form is issued to a person, the Attorney General shall, before delivery thereof, insert therein the name of such person, and it shall be unlawful for any other person (A) to use such form for the purpose of obtaining controlled substances or (B) to furnish such form to any person with intent thereby to procure the distribution of such substances.

(2) The Attorney General may charge reasonable fees for the issuance of such forms in such amounts as he may prescribe for the purpose of covering the cost to the United States of issuing such forms, and other necessary activities in connection therewith.

(e) Unlawful acts

It shall be unlawful for any person to obtain by means of order forms issued under this section controlled substances for any purpose other than their use, distribution, dispensing, or administration in the conduct of a lawful business in such substances or in the course of his professional practice or research.

(Pub. L. 91-513, title II, §308, Oct. 27, 1970, 84 Stat. 1259; Pub. L. 111-273, §3(b), Oct. 12, 2010, 124 Stat. 2860.)

REFERENCES IN TEXT

Schedules I and II, referred to in subsec. (a), are set out in section 812(c) of this title.

AMENDMENTS

2010—Subsec. (b)(3). Pub. L. 111-273 added par. (3).

§ 829. Prescriptions

(a) Schedule II substances

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 503(b) of that Act [21 U.S.C. 353(b)]. Prescriptions shall be retained in conformity with the requirements of section 827 of this title. No prescription for a controlled substance in schedule II may be refilled.

(b) Schedule III and IV substances

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act [21 U.S.C. 353(b)]. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

(c) Schedule V substances

No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.

(d) Non-prescription drugs with abuse potential

Whenever it appears to the Attorney General that a drug not considered to be a prescription drug under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] should be so considered because of its abuse potential, he shall so advise the Secretary and furnish to him all available data relevant thereto.

(e) Controlled substances dispensed by means of the Internet

(1) No controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.

(2) As used in this subsection:

(A) The term “valid prescription” means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by—

- (i) a practitioner who has conducted at least 1 in-person medical evaluation of the patient; or
- (ii) a covering practitioner.

(B)(i) The term “in-person medical evaluation” means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.

(ii) Nothing in clause (i) shall be construed to imply that 1 in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.

(C) The term “covering practitioner” means, with respect to a patient, a practitioner who conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who—

- (i) has conducted at least 1 in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine, within the previous 24 months; and
- (ii) is temporarily unavailable to conduct the evaluation of the patient.

(3) Nothing in this subsection shall apply to—
(A) the delivery, distribution, or dispensing of a controlled substance by a practitioner engaged in the practice of telemedicine; or

(B) the dispensing or selling of a controlled substance pursuant to practices as determined by the Attorney General by regulation, which shall be consistent with effective controls against diversion.

(Pub. L. 91-513, title II, §309, Oct. 27, 1970, 84 Stat. 1260; Pub. L. 110-425, §2, Oct. 15, 2008, 122 Stat. 4820.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (a), (b), (d), and (e)(1), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

Schedules II, III, IV, and V, referred to in subsecs. (a) to (c), are set out in section 812(c) of this title.

AMENDMENTS

2008—Subsec. (e). Pub. L. 110-425 added subsec. (e).

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110-425 effective 180 days after Oct. 15, 2008, except as otherwise provided, see section 3(j) of Pub. L. 110-425, set out as a note under section 802 of this title.

EFFECT OF SCHEDULING ON PRESCRIPTIONS

Pub. L. 101-647, title XIX, §1902(c), Nov. 29, 1990, 104 Stat. 4852, provided that: "Any prescription for anabolic steroids subject to refill on or after the date of enactment of the amendments made by this section [Nov. 29, 1990] may be refilled without restriction under section 309(a) of the Controlled Substances Act (21 U.S.C. 829(a))."

§ 830. Regulation of listed chemicals and certain machines

(a) Record of regulated transactions

(1) Each regulated person who engages in a regulated transaction involving a listed chemical, a tableting machine, or an encapsulating machine shall keep a record of the transaction for two years after the date of the transaction.

(2) A record under this subsection shall be retrievable and shall include the date of the regulated transaction, the identity of each party to the regulated transaction, a statement of the quantity and form of the listed chemical, a description of the tableting machine or encapsulating machine, and a description of the method of transfer. Such record shall be available for inspection and copying by the Attorney General.

(3) It is the duty of each regulated person who engages in a regulated transaction to identify each other party to the transaction. It is the duty of such other party to present proof of identity to the regulated person. The Attorney General shall specify by regulation the types of documents and other evidence that constitute proof of identity for purposes of this paragraph.

(b) Reports to Attorney General

(1) Each regulated person shall report to the Attorney General, in such form and manner as the Attorney General shall prescribe by regulation—

(A) any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated

person believes may indicate that the listed chemical will be used in violation of this subchapter;

(B) any proposed regulated transaction with a person whose description or other identifying characteristic the Attorney General furnishes in advance to the regulated person;

(C) any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person; and

(D) any regulated transaction in a tableting machine or an encapsulating machine.

Each report under subparagraph (A) shall be made at the earliest practicable opportunity after the regulated person becomes aware of the circumstance involved. A regulated person may not complete a transaction with a person whose description or identifying characteristic is furnished to the regulated person under subparagraph (B) unless the transaction is approved by the Attorney General. The Attorney General shall make available to regulated persons guidance documents describing transactions and circumstances for which reports are required under subparagraph (A) and subparagraph (C).

(2) A regulated person that manufactures a listed chemical shall report annually to the Attorney General, in such form and manner and containing such specific data as the Attorney General shall prescribe by regulation, information concerning listed chemicals manufactured by the person. The requirement of the preceding sentence shall not apply to the manufacture of a drug product that is exempted under section 802(39)(A)(iv) of this title.

(3) MAIL ORDER REPORTING.—(A) As used in this paragraph:

(i) The term "drug product" means an active ingredient in dosage form that has been approved or otherwise may be lawfully marketed under the Food, Drug, and Cosmetic Act¹ [21 U.S.C. 301 et seq.] for distribution in the United States.

(ii) The term "valid prescription" means a prescription which is issued for a legitimate medical purpose by an individual practitioner licensed by law to administer and prescribe the drugs concerned and acting in the usual course of the practitioner's professional practice.

(B) Each regulated person who engages in a transaction with a nonregulated person or who engages in an export transaction which—

(i) involves ephedrine, pseudoephedrine, or phenylpropanolamine (including drug products containing these chemicals); and

(ii) uses or attempts to use the Postal Service or any private or commercial carrier;

shall, on a monthly basis, submit a report of each such transaction conducted during the previous month to the Attorney General in such form, containing such data, and at such times as the Attorney General shall establish by regulation.

(C) The data required for such reports shall include—

(i) the name of the purchaser;

¹ See References in Text note below.

(ii) the quantity and form of the ephedrine, pseudoephedrine, or phenylpropanolamine purchased; and

(iii) the address to which such ephedrine, pseudoephedrine, or phenylpropanolamine was sent.

(D) Except as provided in subparagraph (E), the following distributions to a nonregulated person, and the following export transactions, shall not be subject to the reporting requirement in subparagraph (B):

(i) Distributions of sample packages of drug products when such packages contain not more than two solid dosage units or the equivalent of two dosage units in liquid form, not to exceed 10 milliliters of liquid per package, and not more than one package is distributed to an individual or residential address in any 30-day period.

(ii) Distributions of drug products by retail distributors that may not include face-to-face transactions to the extent that such distributions are consistent with the activities authorized for a retail distributor as specified in section 802(49) of this title, except that this clause does not apply to sales of scheduled listed chemical products at retail.

(iii) Distributions of drug products to a resident of a long term care facility (as that term is defined in regulations prescribed by the Attorney General) or distributions of drug products to a long term care facility for dispensing to or for use by a resident of that facility.

(iv) Distributions of drug products pursuant to a valid prescription.

(v) Exports which have been reported to the Attorney General pursuant to section 954 or 971 of this title or which are subject to a waiver granted under section 971(f)(2) of this title.

(vi) Any quantity, method, or type of distribution or any quantity, method, or type of distribution of a specific listed chemical (including specific formulations or drug products) or of a group of listed chemicals (including specific formulations or drug products) which the Attorney General has excluded by regulation from such reporting requirement on the basis that such reporting is not necessary for the enforcement of this subchapter or subchapter II of this chapter.

(E) The Attorney General may revoke any or all of the exemptions listed in subparagraph (D) for an individual regulated person if he finds that drug products distributed by the regulated person are being used in violation of this subchapter or subchapter II of this chapter. The regulated person shall be notified of the revocation, which will be effective upon receipt by the person of such notice, as provided in section 971(c)(1) of this title, and shall have the right to an expedited hearing as provided in section 971(c)(2) of this title.

(c) Confidentiality of information obtained by Attorney General; non-disclosure; exceptions

(1) Except as provided in paragraph (2), any information obtained by the Attorney General under this section which is exempt from disclosure under section 552(a) of title 5, by reason of section 552(b)(4) of such title, is confidential and may not be disclosed to any person.

(2) Information referred to in paragraph (1) may be disclosed only—

(A) to an officer or employee of the United States engaged in carrying out this subchapter, subchapter II of this chapter, or the customs laws;

(B) when relevant in any investigation or proceeding for the enforcement of this subchapter, subchapter II of this chapter, or the customs laws;

(C) when necessary to comply with an obligation of the United States under a treaty or other international agreement; or

(D) to a State or local official or employee in conjunction with the enforcement of controlled substances laws or chemical control laws.

(3) The Attorney General shall—

(A) take such action as may be necessary to prevent unauthorized disclosure of information by any person to whom such information is disclosed under paragraph (2); and

(B) issue guidelines that limit, to the maximum extent feasible, the disclosure of proprietary business information, including the names or identities of United States exporters of listed chemicals, to any person to whom such information is disclosed under paragraph (2).

(4) Any person who is aggrieved by a disclosure of information in violation of this section may bring a civil action against the violator for appropriate relief.

(5) Notwithstanding paragraph (4), a civil action may not be brought under such paragraph against investigative or law enforcement personnel of the Drug Enforcement Administration.

(d) Scheduled listed chemicals; restrictions on sales quantity; requirements regarding non-liquid forms

With respect to ephedrine base, pseudoephedrine base, or phenylpropanolamine base in a scheduled listed chemical product—

(1) the quantity of such base sold at retail in such a product by a regulated seller, or a distributor required to submit reports by subsection (b)(3) may not, for any purchaser, exceed a daily amount of 3.6 grams, without regard to the number of transactions; and

(2) such a seller or distributor may not sell such a product in nonliquid form (including gel caps) at retail unless the product is packaged in blister packs, each blister containing not more than 2 dosage units, or where the use of blister packs is technically infeasible, the product is packaged in unit dose packets or pouches.

(e) Scheduled listed chemicals; behind-the-counter access; logbook requirement; training of sales personnel; privacy protections

(1) Requirements regarding retail transactions

(A) In general

Each regulated seller shall ensure that, subject to subparagraph (F), sales by such seller of a scheduled listed chemical product at retail are made in accordance with the following:

(i) In offering the product for sale, the seller places the product such that cus-

tomers do not have direct access to the product before the sale is made (in this paragraph referred to as “behind-the-counter” placement). For purposes of this paragraph, a behind-the-counter placement of a product includes circumstances in which the product is stored in a locked cabinet that is located in an area of the facility involved to which customers do have direct access.

(ii) The seller delivers the product directly into the custody of the purchaser.

(iii) The seller maintains, in accordance with criteria issued by the Attorney General, a written or electronic list of such sales that identifies the products by name, the quantity sold, the names and addresses of purchasers, and the dates and times of the sales (which list is referred to in this subsection as the “logbook”), except that such requirement does not apply to any purchase by an individual of a single sales package if that package contains not more than 60 milligrams of pseudoephedrine.

(iv) In the case of a sale to which the requirement of clause (iii) applies, the seller does not sell such a product unless the sale is made in accordance with the following:

(I) The prospective purchaser—

(aa) presents an identification card that provides a photograph and is issued by a State or the Federal Government, or a document that, with respect to identification, is considered acceptable for purposes of sections 274a.2(b)(1)(v)(A) and 274a.2(b)(1)(v)(B) of title 8, Code of Federal Regulations (as in effect on or after March 9, 2006); and

(bb) signs the written logbook and enters in the logbook his or her name, address, and the date and time of the sale, or for transactions involving an electronic logbook, the purchaser provides a signature using one of the following means:

(AA) Signing a device presented by the seller that captures signatures in an electronic format. Such device shall display the notice described in clause (v). Any device used shall preserve each signature in a manner that clearly links that signature to the other electronically-captured logbook information relating to the prospective purchaser providing that signature.

(BB) Signing a bound paper book. Such bound paper book shall include, for such purchaser, either (aaa) a printed sticker affixed to the bound paper book at the time of sale which either displays the name of each product sold, the quantity sold, the name and address of the purchaser, and the date and time of the sale, or a unique identifier which can be linked to that electronic information, or (bbb) a unique identifier which can be linked to that information and which is written into the

book by the seller at the time of sale. The purchaser shall sign adjacent to the printed sticker or written unique identifier related to that sale. Such bound paper book shall display the notice described in clause (v).

(CC) Signing a printed document that includes, for such purchaser, the name of each product sold, the quantity sold, the name and address of the purchaser, and the date and time of the sale. Such document shall be printed by the seller at the time of the sale. Such document shall contain a clearly identified signature line for a purchaser to sign. Such printed document shall display the notice described in clause (v). Each signed document shall be inserted into a binder or other secure means of document storage immediately after the purchaser signs the document.

(II) The seller enters in the logbook the name of the product and the quantity sold. Such information may be captured through electronic means, including through electronic data capture through bar code reader or similar technology.

(III) The logbook maintained by the seller includes the prospective purchaser’s name, address, and the date and time of the sale, as follows:

(aa) If the purchaser enters the information, the seller must determine that the name entered in the logbook corresponds to the name provided on such identification and that the date and time entered are correct.

(bb) If the seller enters the information, the prospective purchaser must verify that the information is correct.

(cc) Such information may be captured through electronic means, including through electronic data capture through bar code reader or similar technology.

(v) The written or electronic logbook includes, in accordance with criteria of the Attorney General, a notice to purchasers that entering false statements or misrepresentations in the logbook, or supplying false information or identification that results in the entry of false statements or misrepresentations, may subject the purchasers to criminal penalties under section 1001 of title 18, which notice specifies the maximum fine and term of imprisonment under such section.

(vi) Regardless of whether the logbook entry is written or electronic, the seller maintains each entry in the logbook for not fewer than 2 years after the date on which the entry is made.

(vii) In the case of individuals who are responsible for delivering such products into the custody of purchasers or who deal directly with purchasers by obtaining payments for the products, the seller has sub-

mitted to the Attorney General a self-certification that all such individuals have, in accordance with criteria under subparagraph (B)(ii), undergone training provided by the seller to ensure that the individuals understand the requirements that apply under this subsection and subsection (d).

(viii) The seller maintains a copy of such certification and records demonstrating that individuals referred to in clause (vii) have undergone the training.

(ix) If the seller is a mobile retail vendor:

(I) The seller complies with clause (i) by placing the product in a locked cabinet.

(II) The seller does not sell more than 7.5 grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base in such products per customer during a 30-day period.

(B) Additional provisions regarding certifications and training

(i) In general

A regulated seller may not sell any scheduled listed chemical product at retail unless the seller has submitted to the Attorney General the self-certification referred to in subparagraph (A)(vii). The certification is not effective for purposes of the preceding sentence unless, in addition to provisions regarding the training of individuals referred to in such subparagraph, the certification includes a statement that the seller understands each of the requirements that apply under this paragraph and under subsection (d) and agrees to comply with the requirements.

(ii) Issuance of criteria; self-certification

The Attorney General shall by regulation establish criteria for certifications under this paragraph. The criteria shall—

(I) provide that the certifications are self-certifications provided through the program under clause (iii);

(II) provide that a separate certification is required for each place of business at which a regulated seller sells scheduled listed chemical products at retail; and

(III) include criteria for training under subparagraph (A)(vii).

(iii) Program for regulated sellers

The Attorney General shall establish a program regarding such certifications and training in accordance with the following:

(I) The program shall be carried out through an Internet site of the Department of Justice and such other means as the Attorney General determines to be appropriate.

(II) The program shall inform regulated sellers that section 1001 of title 18 applies to such certifications.

(III) The program shall make available to such sellers an explanation of the criteria under clause (ii).

(IV) The program shall be designed to permit the submission of the certifications through such Internet site.

(V) The program shall be designed to automatically provide the explanation referred to in subclause (III), and an acknowledgement that the Department has received a certification, without requiring direct interactions of regulated sellers with staff of the Department (other than the provision of technical assistance, as appropriate).

(iv) Availability of certification to State and local officials

Promptly after receiving a certification under subparagraph (A)(vii), the Attorney General shall make available a copy of the certification to the appropriate State and local officials.

(v) Publication of list of self-certified persons

The Attorney General shall develop and make available a list of all persons who are currently self-certified in accordance with this section. This list shall be made publicly available on the website of the Drug Enforcement Administration in an electronically downloadable format.

(C) Privacy protections

In order to protect the privacy of individuals who purchase scheduled listed chemical products, the Attorney General shall by regulation establish restrictions on disclosure of information in logbooks under subparagraph (A)(iii). Such regulations shall—

(i) provide for the disclosure of the information as appropriate to the Attorney General and to State and local law enforcement agencies; and

(ii) prohibit accessing, using, or sharing information in the logbooks for any purpose other than to ensure compliance with this subchapter or to facilitate a product recall to protect public health and safety.

(D) False statements or misrepresentations by purchasers

For purposes of section 1001 of title 18, entering information in the logbook under subparagraph (A)(iii) shall be considered a matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States.

(E) Good faith protection

A regulated seller who in good faith releases information in a logbook under subparagraph (A)(iii) to Federal, State, or local law enforcement authorities is immune from civil liability for such release unless the release constitutes gross negligence or intentional, wanton, or willful misconduct.

(F) Inapplicability of requirements to certain sales

Subparagraph (A) does not apply to the sale at retail of a scheduled listed chemical product if a report on the sales transaction is required to be submitted to the Attorney General under subsection (b)(3).

(G) Certain measures regarding theft and diversion

A regulated seller may take reasonable measures to guard against employing indi-

viduals who may present a risk with respect to the theft and diversion of scheduled listed chemical products, which may include, notwithstanding State law, asking applicants for employment whether they have been convicted of any crime involving or related to such products or controlled substances.

(2) Mail-order reporting; verification of identity of purchaser; 30-day restriction on quantities for individual purchasers

Each regulated person who makes a sale at retail of a scheduled listed chemical product and is required under subsection (b)(3) to submit a report of the sales transaction to the Attorney General is subject to the following:

(A) The person shall, prior to shipping the product, confirm the identity of the purchaser in accordance with procedures established by the Attorney General. The Attorney General shall by regulation establish such procedures.

(B) The person may not sell more than 7.5 grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base in such products per customer during a 30-day period.

(C) Each regulated person who makes a sale at retail of a scheduled listed chemical product and is required under subsection (b)(3) to submit a report of the sales transaction to the Attorney General may not sell any scheduled listed chemical product at retail unless such regulated person has submitted to the Attorney General a self-certification including a statement that the seller understands each of the requirements that apply under this paragraph and under subsection (d) and agrees to comply with the requirements. The Attorney General shall by regulation establish criteria for certifications of mail-order distributors that are consistent with the criteria established for the certifications of regulated sellers under paragraph (1)(B).

(3) Exemptions for certain products

Upon the application of a manufacturer of a scheduled listed chemical product, the Attorney General may by regulation provide that the product is exempt from the provisions of subsection (d) and paragraphs (1) and (2) of this subsection if the Attorney General determines that the product cannot be used in the illicit manufacture of methamphetamine.

(Pub. L. 91-513, title II, §310, as added Pub. L. 95-633, title II, §202(a), Nov. 10, 1978, 92 Stat. 3774; amended Pub. L. 100-690, title VI, §6052(a), Nov. 18, 1988, 102 Stat. 4312; Pub. L. 103-200, §§2(c), 10, Dec. 17, 1993, 107 Stat. 2336, 2341; Pub. L. 104-237, title II, §208, title IV, §402, Oct. 3, 1996, 110 Stat. 3104, 3111; Pub. L. 106-310, div. B, title XXXVI, §3652, Oct. 17, 2000, 114 Stat. 1239; Pub. L. 109-177, title VII, §§711(a)(2)(B), (b)(1), (c)(1), (2), (d), 716(b)(2), Mar. 9, 2006, 120 Stat. 257, 261, 267; Pub. L. 110-415, §2, Oct. 14, 2008, 122 Stat. 4349; Pub. L. 111-268, §§2, 3, Oct. 12, 2010, 124 Stat. 2847.)

REFERENCES IN TEXT

The Food, Drug, and Cosmetic Act, referred to in subsec. (b)(3)(A)(i), probably means the Federal Food,

Drug, and Cosmetic Act, act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

This subchapter, referred to in subsecs. (b)(3)(D)(vi), (E) and (e)(1)(C)(ii), was in the original "this title", meaning title II of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1242, and is popularly known as the "Controlled Substances Act". For complete classification of title II to the Code, see second paragraph of Short Title note set out under section 801 of this title and Tables.

Subchapter II of this chapter, referred to in subsecs. (b)(3)(D)(iv), (E) and (c)(2)(A), (B), was in the original "title III", meaning title III of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1285. Part A of title III comprises subchapter II of this chapter. For classification of Part B, consisting of sections 1101 to 1105 of title III, see Tables.

AMENDMENTS

2010—Subsec. (e)(1)(B)(v). Pub. L. 111-268, §3, added cl. (v).

Subsec. (e)(2)(C). Pub. L. 111-268, §2, added subpar. (C).

2008—Subsec. (e)(1)(A)(iv) to (vi). Pub. L. 110-415 added cls. (iv) to (vi) and struck out former cls. (iv) to (vi) which related to procedures for sales subject to the logbook requirement.

2006—Subsec. (b)(3)(D)(ii). Pub. L. 109-177, §711(c)(2), inserted ", except that this clause does not apply to sales of scheduled listed chemical products at retail" before period at end.

Pub. L. 109-177, §711(a)(2)(B), substituted "section 802(49)" for "section 802(46)".

Subsec. (b)(3)(D)(v). Pub. L. 109-177, §716(b)(2), substituted "section 971(f)(2)" for "section 971(e)(2)".

Subsec. (d). Pub. L. 109-177, §711(b)(1), added subsec. (d).

Subsec. (e)(1). Pub. L. 109-177, §711(b)(1), added subsec. heading and par. (1).

Subsec. (e)(2). Pub. L. 109-177, §711(c)(1), added par. (2).

Subsec. (e)(3). Pub. L. 109-177, §711(d), added par. (3).

2000—Subsec. (b)(3). Pub. L. 106-310 added subpars. (A), (D), and (E), redesignated former subpars. (A) and (B) as (B) and (C), respectively, and inserted "or who engages in an export transaction" after "nonregulated person" in introductory provisions of subpar. (B).

1996—Subsec. (a)(1). Pub. L. 104-237, §208, substituted "for two years after the date of the transaction." for the dash after "record of the transaction" and struck out subpars. (A) and (B) which read as follows:

"(A) for 4 years after the date of the transaction, if the listed chemical is a list I chemical or if the transaction involves a tableting machine or an encapsulating machine; and

"(B) for 2 years after the date of the transaction, if the listed chemical is a list II chemical."

Subsec. (b)(3). Pub. L. 104-237, §402, added par. (3).

1993—Subsec. (a)(1). Pub. L. 103-200, §2(c)(1), substituted "list I chemical" for "precursor chemical" in subpar. (A) and "a list II chemical" for "an essential chemical" in subpar. (B).

Subsec. (b). Pub. L. 103-200, §10, designated existing provisions as par. (1), redesignated former pars. (1) to (4) as subpars. (A) to (D), respectively, in concluding provisions, substituted "subparagraph (A)" for "paragraph (1)" in two places, "subparagraph (B)" for "paragraph (2)", and "subparagraph (C)" for "paragraph (3)", and added par. (2).

Subsec. (c)(2)(D). Pub. L. 103-200, §2(c)(2), substituted "chemical control laws" for "precursor chemical laws".

1988—Pub. L. 100-690 amended section generally, substituting provisions relating to regulation of listed chemicals and certain machines for provisions relating to reporting by any person who distributes, sells, or imports any piperidine.

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111-268, §6(a), Oct. 12, 2010, 124 Stat. 2848, provided that: “This Act [amending this section and section 842 of this title and enacting provisions set out as notes under this section and section 801 of this title] and the amendments made by this Act shall take effect 180 days after the date of enactment of this Act [Oct. 12, 2010].”

EFFECTIVE DATE OF 2006 AMENDMENT

Pub. L. 109-177, title VII, §711(b)(2), Mar. 9, 2006, 120 Stat. 261, provided that: “With respect to subsections (d) and (e)(1) of section 310 of the Controlled Substances Act [21 U.S.C. 830(d), (e)(1)], as added by paragraph (1) of this subsection:

“(A) Such subsection (d) applies on and after the expiration of the 30-day period beginning on the date of the enactment of this Act [Mar. 9, 2006].

“(B) Such subsection (e)(1) applies on and after September 30, 2006.”

Pub. L. 109-177, title VII, §711(c)(3), Mar. 9, 2006, 120 Stat. 261, provided that: “The amendments made by paragraphs (1) and (2) [amending this section] apply on and after the expiration of the 30-day period beginning on the date of the enactment of this Act [Mar. 9, 2006].”

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103-200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103-200, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100-690 effective 120 days after Nov. 18, 1988, see section 6061 of Pub. L. 100-690, set out as a note under section 802 of this title.

EFFECTIVE DATE; TIME TO SUBMIT PIPERIDINE REPORT; REQUIRED INFORMATION

Section 203(a) of title II of Pub. L. 95-633 provided that:

“(1) Except as provided under paragraph (2), the amendments made by this title [enacting this section and amending sections 841 to 843 of this title] shall take effect on the date of the enactment of this Act [Nov. 10, 1978].

“(2) Any person required to submit a report under section 310(a)(1) of the Controlled Substances Act [subsec. (a)(1) of this section] respecting a distribution, sale, or importation of piperidine during the 90 days after the date of the enactment of this Act [Nov. 10, 1978] may submit such report any time up to 97 days after such date of enactment.

“(3) Until otherwise provided by the Attorney General by regulation, the information required to be reported by a person under section 310(a)(1) of the Controlled Substances Act (as added by section 202(a)(2) of this title) [subsec. (a)(1) of this section] with respect to the person’s distribution, sale, or importation of piperidine shall—

“(A) be the information described in subparagraphs (A) and (B) of such section, and

“(B) except as provided in paragraph (2) of this subsection, be reported not later than seven days after the date of such distribution, sale, or importation.”

REPEALS

Pub. L. 96-359, §8(b), Sept. 26, 1980, 94 Stat. 1194, repealed section 203(d) of Pub. L. 95-633, which had provided for the repeal of this section effective Jan. 1, 1981.

REGULATIONS

Pub. L. 111-268, §6(b), Oct. 12, 2010, 124 Stat. 2848, provided that: “In promulgating the regulations authorized by section 2 [amending this section], the Attorney General may issue regulations on an interim basis as necessary to ensure the implementation of this Act by the effective date [see Effective Date of 2010 Amendment note above].”

Section 203(b) of Pub. L. 95-633 required the Attorney General to publish proposed interim regulations for piperidine reporting under section 830(a) of this title not later than 30 days after enactment, and final interim regulations not later than 75 days after enactment, such final interim regulations to be effective on and after the ninety-first day after enactment.

REPORT TO PRESIDENT AND CONGRESS ON EFFECTIVENESS OF TITLE II OF PUB. L. 95-633

Section 203(c) of Pub. L. 95-633 required the Attorney General to analyze and evaluate the impact and effectiveness of the amendments made by title II of Pub. L. 95-633, and report to the President and Congress not later than Mar. 1, 1980.

§ 831. Additional requirements relating to online pharmacies and telemedicine**(a) In general**

An online pharmacy shall display in a visible and clear manner on its homepage a statement that it complies with the requirements of this section with respect to the delivery or sale or offer for sale of controlled substances and shall at all times display on the homepage of its Internet site a declaration of compliance in accordance with this section.

(b) Licensure

Each online pharmacy shall comply with the requirements of State law concerning the licensure of pharmacies in each State from which it, and in each State to which it, delivers, distributes, or dispenses or offers to deliver, distribute, or dispense controlled substances by means of the Internet, pursuant to applicable licensure requirements, as determined by each such State.

(c) Internet pharmacy site disclosure information

Each online pharmacy shall post in a visible and clear manner on the homepage of each Internet site it operates, or on a page directly linked thereto in which the hyperlink is also visible and clear on the homepage, the following information for each pharmacy that delivers, distributes, or dispenses controlled substances pursuant to orders made on, through, or on behalf of, that website:

(1) The name and address of the pharmacy as it appears on the pharmacy’s Drug Enforcement Administration certificate of registration.

(2) The pharmacy’s telephone number and email address.

(3) The name, professional degree, and States of licensure of the pharmacist-in-charge, and a telephone number at which the pharmacist-in-charge can be contacted.

(4) A list of the States in which the pharmacy is licensed to dispense controlled substances.

(5) A certification that the pharmacy is registered under this part to deliver, distribute, or dispense by means of the Internet controlled substances.

(6) The name, address, telephone number, professional degree, and States of licensure of any practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the website or at the

request of the owner or operator of the website, or any employee or agent thereof.

(7) The following statement, unless revised by the Attorney General by regulation: “This online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation or medical evaluation via telemedicine in accordance with applicable requirements of section 309.”.

(d) Notification

(1) In general

Thirty days prior to offering a controlled substance for sale, delivery, distribution, or dispensing, the online pharmacy shall notify the Attorney General, in such form and manner as the Attorney General shall determine, and the State boards of pharmacy in any States in which the online pharmacy offers to sell, deliver, distribute, or dispense controlled substances.

(2) Contents

The notification required under paragraph (1) shall include—

(A) the information required to be posted on the online pharmacy’s Internet site under subsection (c) and shall notify the Attorney General and the applicable State boards of pharmacy, under penalty of perjury, that the information disclosed on its Internet site under subsection (c) is true and accurate;

(B) the online pharmacy’s Internet site address and a certification that the online pharmacy shall notify the Attorney General of any change in the address at least 30 days in advance; and

(C) the Drug Enforcement Administration registration numbers of any pharmacies and practitioners referred to in subsection (c), as applicable.

(3) Existing online pharmacies

An online pharmacy that is already operational as of the effective date of this section, shall notify the Attorney General and applicable State boards of pharmacy in accordance with this subsection not later than 30 days after such date.

(e) Declaration of compliance

On and after the date on which it makes the notification under subsection (d), each online pharmacy shall display on the homepage of its Internet site, in such form as the Attorney General shall by regulation require, a declaration that it has made such notification to the Attorney General.

(f) Reports

Any statement, declaration, notification, or disclosure required under this section shall be considered a report required to be kept under this part.

(g) Notice and designations concerning Indian tribes

(1) In general

For purposes of sections 802(52) and 882(c)(6)(B) of this title, the Secretary shall

notify the Attorney General, at such times and in such manner as the Secretary and the Attorney General determine appropriate, of the Indian tribes or tribal organizations with which the Secretary has contracted or compacted under the Indian Self-Determination and Education Assistance Act [25 U.S.C. 450 et seq.] for the tribes or tribal organizations to provide pharmacy services.

(2) Designations

(A) In general

The Secretary may designate a practitioner described in subparagraph (B) as an Internet Eligible Controlled Substances Provider. Such designations shall be made only in cases where the Secretary has found that there is a legitimate need for the practitioner to be so designated because the population served by the practitioner is in a sufficiently remote location that access to medical services is limited.

(B) Practitioners

A practitioner described in this subparagraph is a practitioner who is an employee or contractor of the Indian Health Service, or is working for an Indian tribe or tribal organization under its contract or compact under the Indian Self-Determination and Education Assistance Act [25 U.S.C. 450 et seq.] with the Indian Health Service.

(h) Special registration for telemedicine

(1) In general

The Attorney General may issue to a practitioner a special registration to engage in the practice of telemedicine for purposes of section 802(54)(E) of this title if the practitioner, upon application for such special registration—

(A) demonstrates a legitimate need for the special registration; and

(B) is registered under section 823(f) of this title in the State in which the patient will be located when receiving the telemedicine treatment, unless the practitioner—

(i) is exempted from such registration in all States under section 822(d) of this title; or

(ii) is an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract and is registered under section 823(f) of this title in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 823(f) of this title.

(2) Regulations

The Attorney General shall, with the concurrence of the Secretary, promulgate regulations specifying the limited circumstances in which a special registration under this subsection may be issued and the procedures for obtaining such a special registration.

(3) Denials

Proceedings to deny an application for registration under this subsection shall be conducted in accordance with section 824(c) of this title.

(i) Reporting of telemedicine by VHA during medical emergency situations**(1) In general**

Any practitioner issuing a prescription for a controlled substance under the authorization to conduct telemedicine during a medical emergency situation described in section 802(54)(F) of this title shall report to the Secretary of Veterans Affairs the authorization of that emergency prescription, in accordance with such requirements as the Secretary of Veterans Affairs shall, by regulation, establish.

(2) To Attorney General

Not later than 30 days after the date that a prescription described in subparagraph (A) is issued, the Secretary of Veterans Affairs shall report to the Attorney General the authorization of that emergency prescription.

(j) Clarification concerning prescription transfers

Any transfer between pharmacies of information relating to a prescription for a controlled substance shall meet the applicable requirements under regulations promulgated by the Attorney General under this chapter.

(Pub. L. 91-513, title II, §311, as added Pub. L. 110-425, §3(d)(1), Oct. 15, 2008, 122 Stat. 4825.)

REFERENCES IN TEXT

Section 309, referred to in subsec. (c)(7), is section 309 of Pub. L. 91-513, which is classified to section 829 of this title.

For effective date of this section, referred to in subsec. (d)(3), see Effective Date note below.

The Indian Self-Determination and Education Assistance Act, referred to in subsec. (g)(1), (2)(B), is Pub. L. 93-638, Jan. 4, 1975, 88 Stat. 2203, which is classified principally to subchapter II (§450 et seq.) of chapter 14 of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 450 of Title 25 and Tables.

This chapter, referred to in subsec. (j), was in the original "this Act", meaning Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1236. For complete classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables.

EFFECTIVE DATE

Section effective 180 days after Oct. 15, 2008, except as otherwise provided, see section 3(j) of Pub. L. 110-425, set out as an Effective Date of 2008 Amendment note under section 802 of this title.

PART D—OFFENSES AND PENALTIES

§ 841. Prohibited acts A**(a) Unlawful acts**

Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—

(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or

(2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance.

(b) Penalties

Except as otherwise provided in section 849, 859, 860, or 861 of this title, any person who vio-

lates subsection (a) of this section shall be sentenced as follows:

(1)(A) In the case of a violation of subsection (a) of this section involving—

(i) 1 kilogram or more of a mixture or substance containing a detectable amount of heroin;

(ii) 5 kilograms or more of a mixture or substance containing a detectable amount of—

(I) coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(II) cocaine, its salts, optical and geometric isomers, and salts of isomers;

(III) ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(IV) any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subclauses (I) through (III);

(iii) 280 grams or more of a mixture or substance described in clause (ii) which contains cocaine base;

(iv) 100 grams or more of phencyclidine (PCP) or 1 kilogram or more of a mixture or substance containing a detectable amount of phencyclidine (PCP);

(v) 10 grams or more of a mixture or substance containing a detectable amount of lysergic acid diethylamide (LSD);

(vi) 400 grams or more of a mixture or substance containing a detectable amount of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide or 100 grams or more of a mixture or substance containing a detectable amount of any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide;

(vii) 1000 kilograms or more of a mixture or substance containing a detectable amount of marihuana, or 1,000 or more marihuana plants regardless of weight; or

(viii) 50 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 500 grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers;

such person shall be sentenced to a term of imprisonment which may not be less than 10 years or more than life and if death or serious bodily injury results from the use of such substance shall be not less than 20 years or more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or \$10,000,000 if the defendant is an individual or \$50,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment which may not be less than 20 years and not more than life imprisonment and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or \$20,000,000 if the defendant is an individual or \$75,000,000 if the defendant is other than an individual, or both. If any person commits a viola-